Drug Enforcement Administration

[Docket No. DEA-933]

Bulk Manufacturer of Controlled Substances Application: Navinta LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Navinta LLC, has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on October 18, 2021, Navinta LLC, 1499 Lower Ferry Road, Ewing, New Jersey 08618-1414, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II

Levomethorphan	9210	II
Levorphanol	9220	II
Noroxymorphone	9739	II
Fentanyl	9801	II

The company plans to bulk manufacture active pharmaceutical ingredients (API) quantities of the listed controlled subsances for validation purpose and the Food and Drug Adminstration approval. No other activities for these drug codes are authorized for this registration.

Brian S. Besser,

Acting Assistant Administrator.

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